

**REMARKS**

The Office Action of September 25, 2007, provides the examination of claims 1-8, 15-19, 25, 26, 55, 56, 58 and 59, claims 9-14, 20-24, 27-54, 57, 60 and 61 being withdrawn from consideration following restriction of the claims.

**Double patenting**

Claim 8 remains objected to under 37 CFR § 1.75 as being a substantial duplicate of claim 18. The Examiner maintains the instant objection despite substantial difference in the scope of these claims only because the scope of examination has been limited with respect to an elected species. Applicants will address this objection substantially at the conclusion of prosecution.

**Rejection under 35 USC section 112, second paragraph**

Claims 25 and 26 are rejected under 35 USC 112, second paragraph as being indefinite. The Examiner suggests a remedial amendment to claim 25 to recite, "selected from the group consisting of a change...,". Such amendment has been made, thus obviating this rejection.

**Rejection under 35 USC § 112, first paragraph - written description**

Claims 1-8, 15-19, 25, 26, 55, 56, 58 and 59 are rejected under 35 USC § 112, first paragraph, for alleged lack of written description support by this specification. This rejection is respectfully traversed, reconsideration and withdrawal thereof are requested.

The rejection stems in part from an interpretation of the claims by the Examiner that the N, P. and L proteins of the inventive virus as recited in claim 1 can be obtained from any virus. Claim 1 is amended to clarify that these proteins are those of an HMPV virus. The Examiner

also argues that the present specification provides only to distinct nucleotide sequences of two different strains of HMPV viruses, and she asserts that this evidence is that the Applicants do not have possession of the invention of the broad scope claimed. Applicants strongly disagree. The present specification, including its figures, provides adequate evidence that the Applicants fully possess the invention is described in claim one. The Examiner is reminded that the specification must fully describe the claimed invention, in this case a replication competent, attenuated HMPV. The specification exemplifies the claimed invention using two distinct strains of HMPV. To the degree that the invention is exemplified in the specification by these two strains, which the Examiner admits have diverse nucleotide sequences, operability of the invention is independent of the fine details of the nucleotide sequence of the HMPV strain. Accordingly, the specification plainly evidences possession by the Inventors of an invention of scope commensurate with the instant pending claims and the present rejection should be withdrawn.

Rejection under 35 USC § 112, first paragraph - enablement

Claims 1-8, 15-19, 25, 26, 55, 56, 58 and 59 are rejected under 35 USC 112, first paragraph, for alleged lack of enabling disclosure by the specification. This rejection is respectfully traversed, reconsideration and withdrawal thereof are requested.

The Examiner admits that claims of the scope such that the M2-2 ORF is lacking from the viral genome are enabled. The Examiner goes on to argue though that claims of scope such that the M2-2 ORF is only partially deleted or includes one or more nucleotide substitutions that reduce or ablates expression of the M2-2 ORF are not enabled.

Applicants have difficulty understanding how this argument can be sustained in view of the Examiner's admission. In particular the specification well-establishes that M2-2 is a gene important for controlling the replication of HMPV. Complete deletion of the M2-2 ORF results in an attenuated phenotype of the virus. One of ordinary skill in the art, especially after reading

the present specification, would understand that mutations in the viral genome that result in a decline in activity of the M2-2 ORF would also result in attenuation of viral replication, although possibly to a degree different than that accomplished by complete deletion of the M2-2 ORF.

The Examiner is reminded that statements made in a patent specification must be taken as objectively correct, absent any evidence or detailed sound scientific reasoning by the Examiner to the contrary. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). The Examiner has provided only vague speculation about the possible effects of mutations to the HMPV genome, and this is insufficient to support the instant rejection.

Furthermore, the specification includes description of how to make any particular mutation in the HMPV viral genome and how to test such mutated viruses for a suitable degree of attenuation of replication. See, for example, description beginning at page 28, line 35, and continuing through the end of page 35 at least. See also, for instance, Example 2 beginning at page 65, line 30, which describes production of an HMPV virus including a GFP reporter gene that can be used to easily monitor the level of replication of a virus including any particular mutation or combination of mutations, Example 3 beginning at page 74, line 25, describing the development of a number of mutated HMPV viruses having specified mutations imparting desired phenotypes to the virus, and Example 5 beginning at page 93, line 27 demonstrating the analysis of viral phenotype, including replication levels, in experimental animals.

Applicants submit that for at least the above reasons the Examiner's assertion of lack of enablement is not sustainable and the instant rejection should be withdrawn.

Rejection under 35 USC § 103(a)

Claims 1-4, 6-8, 15, 16, 18, 25, 55 and 56 are rejected under 35 USC §103(a) as being unpatentable over Bermingham et al. (1999) in view of van den Hoogen et al. (2001) and van

den Hoogen et al. (2002). Also, claims 1 and 3-5 stand rejected under 35 USC § 103(a) as being unpatentable over Bermingham et al. (1999) in view of van den Hoogen et al. (2001), van den Hoogen et al. (2002) and further in view of Ludin (1996). These rejections are respectfully traversed, reconsideration and withdrawal thereof are respectfully requested.

As a threshold matter, claim 1 has been amended to incorporate the features of claim 7, not included in the instant rejections, and therefore both of the standing rejections for obviousness are believed by Applicants to be overcome.

The Examiner has also declined to consider the previously filed, unsigned declaration of Dr. Peter Collins. Applicants attach hereto a revised, executed declaration of Dr. Peter Collins in support of patentability of the presently-claimed invention. The Examiner is requested to consider its testimony.

Applicants believe that the standing obviousness rejections are overcome.

Application No. 10/789,400  
Amendment dated December 21, 2007  
Reply to final Office Action dated September 25, 2007

Docket No.: 1173-1061PUS3

## CONCLUSION

Applicants submit that the present application well-describes and enables patentable subject matter. The favorable actions of withdrawal of the standing rejections and allowance of the pending claims are respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,625 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: December 21, 2007

Respectfully submitted,

By Mark J. Nuell  
Mark J. Nuell  
Registration No.: 36,623  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
12770 High Bluff Drive  
Suite 260  
San Diego, California 92130  
(858) 792-8855  
Attorney for Applicants

Attachment: Executed Declaration of Peter L. Collins